Exhibit 26

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Memorandum

Date DEC 5 1997

From June Gibbs Brown
Inspector General

Subject OIG Final Report: "Excessive Medicare Payments for Prescription Drugs," OEI-03-97-00290

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

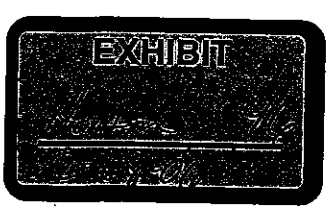
Attached is our final inspection report that compares Medicare allowances for drugs with drug acquisition prices available to the physician and supplier communities.

Medicare allowances for 22 drugs exceeded actual wholesale prices by $447 million in 1996. For the 22 drugs reviewed, Medicare payments would have been reduced by 29 percent if actual wholesale prices had been used instead of manufacturers published wholesale prices.

For more than one-third of the 22 drugs reviewed, Medicare and its beneficiaries paid more than double the actual average wholesale price available to physicians and suppliers. For every one of the 22 drugs reviewed, Medicare reimbursed more than the average actual price in both 1995 and 1996. Not only did Medicare allow more than the average price, the program reimbursed more than even the highest wholesale price for every drug.

We also found there is no consistency among carriers in establishing and updating Medicare drug reimbursement amounts. In some cases, the difference in allowed amounts for the same drug were significant.

The information in this report provides further support for a recommendation made in an earlier report entitled "Medicare Payments for Nebulizer Drugs" where we advised that the Health Care Financing Administration (HCFA) reexamine its Medicare drug reimbursement methodologies with a goal of reducing payments as appropriate The HCFA concurred with the recommendations. In this report, we also recommended that HCFA require all carriers to reimburse a uniform allowed amount for each Common Procedural Coding System drug code



We support HCFA's continued effort to reduce drug payments where appropriate. We do not believe that the new reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments identified in the Medicare program.

If you have any questions or comments about this report, please call me or George Grob, Deputy Inspector General for Evaluation and Inspections, or have your staff contact Mary Beth Clarke at (202) 619-2481.

Attachment

cc:

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DATE: OCT - 1 1997

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle NMD
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Excessive Medicare Payments for Prescription Drugs," (OEI-03-97-00290)

We reviewed the above-referenced report that examines Medicare payments for prescription drugs. Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the 2 years.

Medicare does not pay for over-the-counter drugs or many prescription drugs that are self-administered. However, the program will pay for certain categories of drugs used by its beneficiaries. Contracted carriers determine the amounts that Medicare will pay for the drugs based on the lower of the estimated acquisition cost (EAC) or the national average wholesale price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. OIG findings indicate that at present, it is the AWP that carriers use to develop Medicare reimbursement for prescription drugs. The AWP is reported in The Red Book and other pricing publications and databases used by the pharmaceutical industry. The EAC is determined based on surveys of the actual invoice prices paid for the drug.

The findings contained in the report indicate that Medicare is making excessive payments for prescription drugs. The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs.

OIG suggests that the Health Care Financing Administration (HCFA): (1) reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments; and (2) require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code.

HCFA concurs with OIG's recommendations. Our detailed comments are as follows:

OIG Recommendation 1

HCFA should require all carriers to reimburse a uniform allowed amount for each HCPCS drug code.

HCFA Response

We concur. HCFA agrees with OIG's findings and recommendations contained in this report. HCFA convened a workgroup to develop an electronic file consisting of the AWPs for drugs covered by Medicare. HCFA will then distribute this file to Medicare contractors for their use in paying claims for drugs.

OIG Recommendation 2

HCFA should reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.

HCFA Response

We concur. We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

EXCESSIVE MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS

JUNE GIBBS BROWN
Inspector General

DECEMBER 1997
OEI-03-97-00290

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Philadelphia Regional Office prepared this report under the direction of Robert A. Vito, Regional Inspector General. Principal OEI staff included:

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To obtain copies of this report, please call the Philadelphia Regional Office at (800) 531-9562.

EXECUTIVE SUMMARY

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the 2 years.

Medicare does not pay for over-the-counter or many prescription drugs that are self-administered. However, the program does pay for certain categories of drugs used by Medicare beneficiaries.

On January 1, 1998, Medicare Part B will begin to reimburse covered drugs at 95 percent of the average wholesale price. Currently, Medicare carriers may determine the amounts that Medicare will pay for these drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is reported in *The Red Book* and other pricing publications and databases used by the pharmaceutical industry. Historically, it has been the AWP that carriers have used to develop Medicare reimbursement for prescription drugs.

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on 22 drug codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

FINDINGS

Medicare allowances for 22 drugs exceeded actual wholesale prices by $447 million in 1996.

Medicare and its beneficiaries payments for the 22 drugs would have been reduced by an estimated 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP's were the basis for Medicare reimbursement. Similar savings of $445 million were also identified for 1995. If the savings percentage for just the 22 drugs was applied to Medicare's allowances for all drugs, the program and its beneficiaries would have saved an estimated $667 million in 1996.

For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. Medicare allowed at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed amounts were more than the actual average wholesale price in both 1995 and 1996. Not only did Medicare pay more than the actual average wholesale price, the program allowed more than the highest average wholesale price for every drug.

There is no consistency among carriers in establishing and updating Medicare drug reimbursement amounts.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

RECOMMENDATIONS

The findings of this report provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs.

We believe the information in this report provides further support for a previous recommendation made by the Office of Inspector General. **We recommended that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.** Beginning in January 1998, Medicare reimbursement for prescription drugs will be 95 percent of average wholesale price. We believe that the 5 percent reduction is not a large enough decrease and that further options to reduce reimbursement should be considered.

We also believe that the variance of Medicare reimbursement for individual drug codes among carriers is inappropriate. The rate at which physicians and suppliers are paid for drugs should not depend on which carrier the providers bill. **We, therefore, recommend that HCFA require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code.** The HCFA could choose to supply all carriers with a list of average wholesale prices that it has determined represent each drug code. The carriers could then use the uniform prices to calculate payment. The HCFA could also designate one single entity to perform all

necessary calculations to determine reimbursement for each drug code on a quarterly basis. All carriers would then use this standard reimbursement amount.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress. However, the agency states that it will continue to pursue this policy in other appropriate ways.

We support HCFA's continued pursuance of reducing drug payments where appropriate. We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities.

To address the issue of uniformity among carriers, HCFA has convened a workgroup to develop an electronic file consisting of the average wholesale prices for drugs covered by Medicare. The agency reports it will distribute this file to Medicare contractors for their use in paying drug claims.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the two years.

Medicare Coverage and Payment for Prescription Drugs

While Medicare does not pay for over-the-counter or many prescription drugs that are self-administered, it does pay for certain categories of drugs used by Medicare beneficiaries. Under certain circumstances, Medicare Part B covers drugs that are used with durable medical equipment or infusion equipment. Medicare will cover certain drugs used in association with dialysis or organ transplantation. Drugs used for chemotherapy and pain management in cancer treatments are also covered. The program also covers certain types of vaccines such as those for flu and hepatitis B.

Depending on the type of drug, both local carriers and four Durable Medical Equipment Regional Carriers (DMERCs) are responsible for processing claims for drugs covered under Part B of the Medicare program. The carriers are responsible for determining the allowance that Medicare will pay for these drugs.

Carriers base their current allowance rates on the regulations established in 42 Code of Federal Regulation 405.517. According to the regulations, Medicare computes an allowed amount for drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is determined through *The Red Book* or similar pricing publications and databases used by the pharmaceutical industry. The AWPs are mainly provided to these sources by pharmaceutical manufacturers. If a drug has multiple sources (more than one brand or generic version), the price is based on the lower of the EAC or the median of the national AWP for all generic sources. Historically, carriers have utilized AWP and not estimated acquisition cost to develop Medicare reimbursement for prescription drugs.

Drugs are billed to the Medicare program based on codes developed by the Health Care Financing Administration (HCFA). These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand

or generic version of the drug was administered; nor do the codes provide information on the manufacturer or distributor of the drug provided.

Change in Medicare Reimbursement for Prescription Drugs

In recent legislation, Congress established reimbursement for prescription drugs at 95 percent of a drug's average wholesale price. This change will be implemented on January 1, 1998.

A different proposal to change the Medicare reimbursement methodology for prescription drugs was included in the President's FY 1998 budget. The proposal provided for the amendment of 42 U.S.C. 1395u(o) to set payment for drugs not otherwise paid on a cost or prospective payment basis. The revision set payment at the lowest of: actual acquisition cost to the provider, AWP, median actual acquisition cost, or an amount otherwise determined under the Code. The actual acquisition cost was defined to include all discounts, rebates, or any other benefit in cash or in kind. This proposal was supported by HCFA but was not the version eventually adopted by Congress.

Related Work by the Office of Inspector General

This report is one of several Office of Inspector General reports concerning Medicare payments for prescription drugs. In 1996, we released a report entitled *Appropriateness of Medicare Prescription Drug Allowances* (OEI-03-96-00420) which compared Medicare drug reimbursement mechanisms with Medicaid payment mechanisms for 17 drugs and found that Medicare could achieve significant savings by adopting reimbursement strategies similar to those used by Medicaid. The OIG has also produced several reports focusing on inhalation drugs paid for by Medicare. In *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390), we found that Medicaid reimbursed albuterol sulfate and other nebulizer drugs at significantly lower prices than Medicare. In a companion report called *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392), we found that many retail and mail-order pharmacies charge customers less for generic albuterol sulfate than Medicare's allowed price. *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393) found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs.

The Office of Inspector General also recently issued a report on acquisition costs of brand name drugs by Medicaid pharmacies. In *Medicaid Pharmacy - Actual Acquisition Costs of Prescription Drug Products for Brand Name Drugs* (A-06-96-00030), the Office of Audit Services estimated that the actual acquisition cost for brand name drugs was 18 percent below AWP.

METHODOLOGY

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on drug

codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

We collected from three sources the data needed to compare Medicare allowed amounts to actual wholesale prices. For information on Medicare allowances for prescription drugs, we compiled statistics from HCFA's National Claims History (NCH) File. We then collected Medicare reimbursement rates for specific drugs from contracted carriers. Lastly, we analyzed wholesale prices from drug wholesalers and group purchasing organizations.

Medicare Allowance Data for Prescription Drugs

We decided to review the 30 drug codes with the highest Medicare allowances for 1995. We chose 1995 since the Medicare claims data was 98 percent complete at the commencement of the inspection. To determine the Medicare allowances for prescription drugs in 1995, we compiled a list of HCPCS codes that represent all of the drugs which Medicare reimburses. The drug code list primarily contained HCPCS codes beginning with a J (known as J codes) which represent mainly injectable drugs or drugs used in conjunction with durable medical equipment. Also included in our list of drugs were K codes which usually represent immunosuppressive drugs, Q codes which represent mainly drugs used for End Stage Renal Disease, several A codes that represent drugs used for diagnostic imaging, and immunization or vaccine codes that are represented by a five digit numeric code.

We then retrieved NCH allowance and utilization data using HCFA's Part B Extract and Summary System (BESS). We aggregated the allowances for each code to calculate Medicare's total prescription drug allowance for 1995. We then determined the 30 drug codes with the highest individual allowances for that year.

Using NCH data, we calculated the Medicare allowances for all drugs in 1996. We also determined the 1996 allowances for the 30 drug codes with the highest allowances in 1995. At the time of our inspection, the NCH data for 1996 was 95 percent complete.

Carrier Allowances for Prescription Drugs

We sent requests for carrier drug reimbursement rates to Medicare's 26 fraud information specialists. The fraud information specialists coordinate work among all HCFA contractors in the regions they represent. There are a total of 61 geographical regions that local carriers cover. We received drug allowances from 50 of the 61 areas. We also received responses from two of the four DMERCS.

We requested allowed amounts for prescription drug codes with the highest total allowances in 1995. The allowed amount reflects the dollar reimbursement that Medicare will allow for the specific dosage defined by the HCPCS drug code. We

asked the carriers to provide allowed amounts by quarter for calendar years 1995, 1996, and 1997. However, some carriers provided us with data on a yearly basis and others only for certain quarters.

Some carriers also furnished allowed amounts for both participating and non-participating physicians. Physicians participating in the Medicare program agree to accept Medicare allowed amounts as total reimbursement for their services. Participating physicians receive 5 percent more in Medicare reimbursement for services. In the instances where both participating and non-participating allowed amounts were provided, we used the participating physician allowed amounts. More than three-quarters of physicians across the nation now participate in the Medicare program.

Utilizing the data provided by carriers, we calculated an average Medicare allowed amount for each drug code by year. These allowed amounts were used to compare Medicare reimbursement with drug acquisition costs for physicians and suppliers.

Prescription Drug Costs for Physicians and Suppliers

In order to determine acquisition costs for the top drugs, we reviewed 1995 and 1996 prices offered by wholesale drug companies and group purchasing organizations (GPOs). We obtained pricing lists/catalogs for seven wholesale drug companies and seven group purchasing organizations. Group purchasing organizations provide members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or a drug wholesaler that agrees to accept the negotiated price. For the GPOs we reviewed, most of the major drug wholesalers accept the GPO contracted price.

The 14 pricing sources we used provided pharmaceutical products mainly to physician practices and specialized or closed pharmacies. Depending on individual State licensing practices, specialized or closed pharmacies normally do not provide retail prescription drug dispensing to walk-in customers. Instead, they often provide prescription drugs for home infusion or inhalation therapy.

After beginning our review of wholesale drug costs, we determined that 2 of the top 30 drugs codes we identified for 1995 could not be used for the inspection. Code J7699 represents not-otherwise-classified inhalation drugs and Code J7190 for Factor VIII (human anti-hemophilic factor) has a dosage requirement that is difficult to determine. Therefore, obtaining wholesale prices for these two codes would not be possible.

For the remaining 28 drug codes identified for our analysis, 17 were used for the treatment of cancer/leukemia, 5 were inhalation drugs, 2 were vaccines, and 2 were used for organ transplantation or valve replacement complications. There was also a drug used for immunodeficiencies and another for severe infections. The majority of

these drugs would most likely be purchased and administered by physicians or other health care practitioners. The inhalation drugs or drugs used for home infusion would most likely be provided by a specialized pharmacy or supplier.

For the 28 drug codes, we collected 1995 and 1996 prices from the 14 drug pricing lists/catalogs. We decided not to present prices for drugs where fewer than two different pricing sources could be identified per year. There were 6 codes that did not meet the two source minimum. These codes were: vaccine codes 90724 and 90732, inhalation codes J7645 and J7660, and codes K0121 and J1245 used for transplants/valve replacements. A list of the HCPCS codes' descriptions and dosages for the final 22 drugs used for our evaluation is provided in Appendix A.

The 22 drug codes represented 10 single-source, 9 multiple-source, and 3 multiple-brand drugs. A single-source drug has only one brand of drug available. A multiple-source drug has both brand and generic forms of the drug available. There were no drug products manufactured in the dosage defined by the HCPCS code for five drugs (J7620, Q0136, J2405, J9181, J9293). We selected all the drugs with higher dosages that met the drug description and applied a conversion factor to achieve prices for the HCPCS-specified dosage. For an additional code (J1561), we found that out of the multitude of prices we could find for the drug only three met the exact dosage requirement. Since the higher dosage products seemed to be the more prevalent way of purchasing this drug, we included them in our analysis.

We searched the 14 price lists for both brand and generic prices during 1995 and 1996. For nine drug codes, we obtained between 5 and 8 separate prices. Eight of the nine were single-source drugs. For another eight codes, we found between 12 and 29 separate prices. We found between 30 and 70 separate prices for the remaining five drug codes.

Calculation of Potential Medicare Savings for Prescription Drugs

To determine the potential savings to Medicare if acquisition costs rather than published AWPs were used for reimbursement, we compared Medicare's allowed amounts to the wholesale prices we collected. To do this, we compiled all the pricing information from the sources reviewed and calculated an average price by year for all 22 codes. We believe that the pricing information supplied by the drug wholesalers and group purchasing organizations provides factual evidence of acquisition costs available to physicians and suppliers.

The average price or average acquisition cost for each drug code was then compared to the average Medicare allowed amount that we calculated from the carrier data. For each drug code, the difference between the average price and the Medicare allowed amount was computed. We then applied this amount to the number of services paid by Medicare for each drug in 1995 and 1996. The resulting dollar amounts were aggregated to determine the total estimated savings to Medicare if acquisition costs rather than AWP had been used to determine reimbursement.